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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,009	11/21/2002	Ian Frazer	10905.0003.PCUS00	5472

7590 05/23/2003

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[REDACTED] EXAMINER

SALIMI, ALI REZA

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1648

DATE MAILED: 05/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>09/868,009</b>	Applicant(s) <b>Frazer et al</b>		
	Examiner <b>A. R. SALMI</b>	Art Unit <b>1648</b>		
<b>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</b>				
<b>Period for Reply</b> A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>One</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.				
- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).				
<b>Status</b>				
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Jul 19, 2002</u>				
2a) <input type="checkbox"/> This action is FINAL.      2b) <input type="checkbox"/> This action is non-final.				
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.				
<b>Disposition of Claims</b>				
4) <input checked="" type="checkbox"/> Claim(s) <u>1-33</u> is/are pending in the application.				
4a) Of the above, claim(s) _____ is/are withdrawn from consideration.				
5) <input type="checkbox"/> Claim(s) _____ is/are allowed.				
6) <input type="checkbox"/> Claim(s) _____ is/are rejected.				
7) <input type="checkbox"/> Claim(s) _____ is/are objected to.				
8) <input checked="" type="checkbox"/> Claims <u>1-33</u> are subject to restriction and/or election requirement.				
<b>Application Papers</b>				
9) <input type="checkbox"/> The specification is objected to by the Examiner.				
10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).				
11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.				
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.				
<b>Priority under 35 U.S.C. §§ 119 and 120</b>				
13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).				
a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received.				
14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.				
15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.				
<b>Attachment(s)</b>				
1) <input type="checkbox"/> Notice of References Cited (PTO-892)				
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)				
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____				
4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____				
5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)				
6) <input type="checkbox"/> Other: _____				

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## **DETAILED ACTION**

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1648.

### ***Claim Objections***

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered second no claim 13 has been renumbered 14.

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered second no claim 32 has been renumbered 33.

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*Specification*

The amendment filed 8/14/2001 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: PV L2 VLPs, which has been added throughout the claims. Please note, L2 of a papillomavirus does not form a VLP. A PV L1 does form a VLP and a fusion of L1 and L2 form a PLV, as original claims had indicated.

Applicant is required to cancel the new matter in the reply to this Office Action.

*Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, 11-14, 29-33, drawn to method of treating infection. (**Please note if this group is selected further select one virus type as now listed in claim 4, and one adjuvant as now listed in claim 31 to be examined on the merits, and amend the claims accordingly, see below for explanation)**)

Group II, claim(s) 6, 8, 9, 10, drawn to method of producing PV VLP.

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Group III, claim(s) 1, 7, drawn to method of treating infection by gene therapy.

Group IV, claim(s) 15-20, drawn to method of immunizing against HPV 11.

Group V, claim(s) 21-25, drawn to method of immunizing against HPV 6.

Group VI, claim(s) 26-28, drawn to method of treatment of existing papillomavirus infection.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The invention of Group I is known in the prior art as evidence by Gupta et al ( WO 98/10790) wherein the reference teaches the invention now being claimed ( see the abstract, and the claims). The cited evidence prove that the technical feature of Group I does not make a contribution over the prior art. Thus, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2.

Upon election of Group I, Applicants are additionally required to elect element(s) identified, as indicated above as they apply to group(s). The recited element(s) identified have different structures one from other and the search for the all would be unduly burdensome. The products utilized are made by different methods and have different uses and delineate different results, and have different effect on interaction, antigenicity and immune response. This requirement is not to be construed as a requirement for an election of species, since each of the

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recited elements is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (703) 305-7136. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 305-3014, or (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A. R. Salimi

5/23/2003



ALI R. SALIMI  
PRIMARY EXAMINER